



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM:

To: Jessica Rogala

From: Jacquelyn Marchese, Entomologist

Jacquelyn Marchese

Secondary Review: Pesticide Efficacy Review Committee (PERC)

[Signature]

Date: April 19, 2016

Subject: PRODUCT PERFORMANCE DATA EVALUATION RECORD (DER)

THIS DER DOES NOT CONTAIN CONFIDENTIAL BUSINESS INFORMATION

Note: MRIDs found to be **unacceptable** to support label claims should be removed from the data matrix.

DP barcode: 432328

Decision no.: 506635

Submission no: 983166

Action code: R314

Product Name: RF 2224 AFAB

EPA Reg. No or File Symbol: 89459-IG

Formulation Type: granular insecticide

Ingredients statement from the label with PC codes included:

(S)-Methoprene, 0.500% PC: 105402

Abamectin, 0.011% PC: 122804

Application rate(s) of product and each active ingredient (lbs. or gallons/1000 square feet or per acre as appropriate; and g/m² or mg/cm² or mg/kg body weight as appropriate): 3-5 tablespoons of product per mound = 0.225-0.375 grams of (S)-Methoprene, and 0.0049-0.0083 grams of abamectin per mound.

Use Patterns: Apply product to kill fire ants by sprinkling the product on areas adjacent to the mound, applying evenly in a manner to encompass the mound to a perimeter of 4 feet. No more than 4 pounds of product is to be applied per acre per year. It is also proposed that broadcast applications may also occur with this product. The product is then to be applied at a rate of 1 to 1.5 pounds of product per acre (2.3-3.4 grams of (S)-Methoprene, and 0.049-0.075 grams of abamectin) per acre per year.

I. Action Requested: The original efficacy review determined that the data did not support fire ant claims, as the product worked too slow to kill a public health pest. The registrant argued that the timeframe presented in the data is appropriate for a fire ant bait. The registrant therefore requested that the data package and the acceptable timeframe for fire ant baits be revisited.

II. Background: On 3/2/2016 the registrant submitted an email rebuttal to the 2/10/2016 efficacy review# 428464, DP. The 2/10/2016 document reviewed studies submitted in support of the proposed product and its efficacy against fire ant mounds. The review rated the studies "supplemental" and not "acceptable" because although 90% kill of the mounds was generally observed, the speed in which 90% efficacy was reached was considered too slow.

III. Rebuttal

Central Garden & Pet Point #1: The studies we submitted show our product performs better than the currently registered Syngenta product, which does have fire ant claims.

Please kindly explain why our product, which performs better than the existing product, cannot have those claims.

EPA Rebuttal Point #1:

The determination of the efficacy of a product will not be made based on comparisons to the performance of currently registered products. Performance is evaluated based on the submitted/cited data for the subject product of the review.

Central Garden & Pet Point #2:

The centerpiece of the Agency's review seems to be a conclusion that RF2224 AFAB acts too slowly to be considered effective. But, baits do work slower than contact killers and this is a bait. Some of these are field studies and in addition, some were published by state agricultural extension agents. **This IS acceptable performance** for agricultural field applications.

EPA Rebuttal Point #2

Five MRIDs with 9 studies were submitted in support of product performance against fire ant mounds. In all of these studies the performance of the active ingredients varied. Ninety percent efficacy against fire ant mounds was demonstrated at any time between 6 weeks to 8 months post-treatment, or not at all for the duration of a study (a summary of the performances of the active ingredients in these studies is below).

- MRID 44526001 presented data that demonstrated different levels of efficacy with a 0.5% methoprene product applied at a rate of 1.5 pounds of product per acre. Five studies were submitted in this MRID; the first two did not give data useful to this review. Out of the remaining three studies, ninety percent efficacy was not seen in study #1, though 90% was reported at 8 months for study #2). Ninety percent efficacy was demonstrated at 12 weeks and 6 months for study #3. All of the studies in this MRID did not test a product specific formulation, it will remain **supplemental**.
- Neither of the abamectin nor methoprene products tested in MRID 49667910 demonstrated 90% efficacy for the duration of the study (observations were made at 11 and 32 weeks). Products were applied at a rate of 1.5 pounds of product per acre ((S)-methoprene was tested at 0.500% and abamectin was tested at 0.011%). This study did not test product specific formulations, it will remain **supplemental**.
- Ninety percent control was reached at 14 and 16 weeks for a methoprene product in MRID 49667911. Products were applied at the rate of 1.08 pounds of product per acre*, ((S)-methoprene was tested at 0.500%). This study did not test product specific formulations, it will remain **supplemental**.
- MRID 49667912 presented data that demonstrated 90% control at 12 weeks for experimental formulation A and experimental formulation B, two formulations that are identical to the proposed product, 89459-IG. Experimental formulation A demonstrated 90% efficacy at 12 weeks post-treatment, whereas experimental formulation B demonstrated 90% efficacy at 12 and 16 weeks post treatment. Products were applied at the rate of 1.5 pounds of product per acre ((S)-methoprene was tested at 0.500% and abamectin was tested at 0.011%). This study will be upgraded to **acceptable**.
- MRID 49667913 presented data that demonstrated ninety percent control by the abamectin only product at 8, 12, and 16 weeks, and at 6, 8, 12, and 16 weeks post treatment for the methoprene product. This study also tested the two formulations identical to 89459-IG (experimental formulation A and experimental formulation B). Experimental formulation A, reduced fire ant mounds by 90% at 8, 12, and 16 weeks post treatment, and experimental formulation B, reduced fire ant mounds by 90% at 12, and 16 weeks post treatment. Products were applied at the rate of 1.5 pounds of product per acre ((S)-methoprene was tested at 0.500% and abamectin was tested at 0.011%). This study will be upgraded to **acceptable**.

*Although 1.08 pounds of product per acre was tested in this particular study, it was only tested on methoprene. Abamectin was not tested at this rate and thus 1.5 pounds of product per acre is the lowest rate supported by these studies.

Central Garden & Pet Point #3:

As a further demonstration, I attach a comparative field study of the efficacy of several other fire ant baits (Schofield et al. 2008). At 10 weeks after application, only one of the products showed 90% control of fire ants relative to the control.

EPA Rebuttal Point #3:

Thank you for the additional information. Additional studies are not considered during rebuttals. New studies may only be reviewed when submitted with a new PRIA action.

Central Garden & Pet Conclusion:

Because the performance of all of these products is slow, and their claims have been accepted by the agency, you must conclude that the performance of our product is acceptable.

EPA Conclusion:

The studies demonstrate that the product can provide 90% control of fire ant mounds as quickly as 8 weeks post treatment, but the active ingredients in the product can take as long as 8 months to be effective (at the rate of 1.5 lbs of product per acre (2.3-3.4 grams of (S)-methoprene, and 0.049-0.075 grams of abamectin)). Other baits containing active ingredients with a faster mode of action are known to work as quickly as 1 week against fire ant mounds. The submitted data support that the product can work as quickly as 8 weeks against fire ant mounds, when applied at 1.5 pounds of product per acre.

IV. EXECUTIVE DATA SUMMARY:

(A) The submitted data support that the product will kill fire ant mounds starting at 8 weeks post treatment, when applied at 1.5 pounds of product per acre. All claims should indicate that the product works starting at 8 weeks post treatment.

V. LABEL RECOMMENDATIONS:

(1) List changes to the directions for use. Be specific, listing what needs to be revised or deleted by referencing page number or section header.

- Any reference to an ant mound must be specified as a fire ant mound and that it will not be effective until 8 weeks post application.
- Product must be applied at 1.5 pounds of product per acre to be efficacious at 8 weeks against fire ants
- Page 8 directs the applicator to use additional products for “quick kill,” “speed-up kill,” “immediate control,” and “faster kill.” An additional statement is needed to clarify that a faster kill can only be expected if the label of the additional product has appropriate, approved “quick kills” claims.
- The following must be removed from the Directions For Use
 - “RF2224 is highly attractive to imported and native fire ants.”
 - “This two-way action ensures complete control of fire ants.”
 - “The IGR prevents rebound of the colony, while the adulticide ensure demise* of the colony.”
 - “The mound is destroyed* when the queen dies.”

* “destroy” and “demise” are words that suggest heightened efficacy and are not supported as label claims.

(2) The following marketing claims are acceptable:

- To control fire ants (red imported fire ant, imported fire ant, native fire ant, southern (California) fire ant) at 8 weeks after application
- Controls colonies you see 8 weeks after application

- A dual active bait containing an Insect Growth Regulator and adulticide for control of fire ants, 8 weeks after application.

(3) The following marketing claims are unacceptable:

- Eliminates the colony
- Eliminates fire ant colonies
- Breaking the reproductive life cycle of the ants
- Controls colonies you don't see
- Highly effective
- Kills fire ant colonies within 21 days
- No mound rebound
- Sterilizes the queen
- No mound movement
- Stops the development of new mounds
- Stops new mounds from starting
- A dual active bait slowly kills fire ant workers